WHO Emergency Use Listing/Prequalification of COVID-19 Vaccines

01 October 2020
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WHO preparedness activities for Covid 19 vaccines

Launch of the Expression of Interest (EOI) for candidate vaccines at latest stages of clinical development

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Public consultation of “Considerations for the assessment of Covid 19 vaccines” – comments due by 8th October

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/
Features of PQ and EUL

**Prequalification (PQ) 1987**

- Review of extensive quality, safety and efficacy and PSPQ for international supply
- Assessment performed by WHO independent experts
- Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-PQ monitoring
- Reassessment/requalification

**Emergency Use Listing (EUL) 2015**

- Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs
- Rolling review of data
- Assessment performed by WHO independent experts in collaboration with Mature Regulatory Authorities (WLA)
- Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-deployment monitoring
- Time limited recommendation
- Development should continue for MA/PQ
Expression of Interest (EOI) for EUL/PQ

What does this mean in practice?

- EUL/PQ - WHO led processes for advice on the quality, safety, efficacy and programmatic suitability, especially for LMIC supply.

- COVAX Advanced Marketing Commitment (AMC) can be based on Prequalification (PQ) or WHO Emergency Use Listing (EUL)

- Provides clear and transparent information for manufacturers for an evaluation by WHO.

- Enables end to end approach once efficacy is demonstrated.

An enabler for global access to COVID-19 vaccines to address the pandemic
Who can express interest to apply? (EOI)

Eligibility
Candidate vaccines
• Phase IIb/Phase III
• Regulatory decision within 6 months

Meet WHO Criteria
• Target product profile
• Norms and standards
• PQ/EUL

Alignment with policy recommendation (SAGE)
Part of WHO strategies to support access to COVID-19 vaccines

Development of regional/global strategies

1. Involvement of regulators in review of applications submitted to WHO

2. Regional approach for expedited authorizations:
   - Promotion of reliance principles in order to facilitate the decision making process
   - Sharing reports with all regulatory authorities
   - WHO member states have the sovereignty for decision-making

3. Regional strategy for post-listing monitoring.
**What WHO is putting in place?**

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<th>Global cooperation and coordination on regulation</th>
<th>Facilitation of authorization at global level</th>
<th>Mechanisms for</th>
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<td>1. Review of data for emergency authorization and facilitation in other countries</td>
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<td>2. Monitoring performance for quality, safety, efficacy and programmatic</td>
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<td>3. Collaboration between MS</td>
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Think out of the box, Unite, Collaborate & Cooperate
Path forward

- Pre-submission request opened immediately
- Extent of data and regulatory approvals will determine timelines and pathways
- Working in parallel on labelling, barcodes, safety monitoring, etc.
- Timelines will depend on read-out of successful phase III
- Independence of scientific review

Confidence on quality, safety and efficacy is key
Additional information EUL

Procedure and Questions and Answers

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Target product profile


More information - EUL@who.int
Department of Regulation and Prequalification, WHO